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Original Article

The impact of nocturnal oxygen desaturation on quality of life in cystic fibrosis ☆

Alan C. Young [a,b,*], John W. Wilson [a,b], Tom C. Kotsimbos [a], Matthew T. Naughton [a,b]

[a] *Department of Allergy Immunology and Respiratory Medicine, The Alfred Hospital, Melbourne, Victoria, 3004, Australia*
[b] *Department of Medicine, Monash University, Melbourne, Victoria, 3800, Australia*

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Abstract

Background: Nocturnal oxyhaemoglobin desaturation is common in cystic fibrosis (CF) but the effect on quality of life (QoL) remains unknown.
Methods: Sixty stable CF outpatients with mean age 31±8 years (mean±1SD), BMI 20.8±3.2 kg/m^2 and FEV_1 42±13% predicted had arterial blood gas sampling, lung function testing, overnight pulse oximetry and completed the CF QoL questionnaire, Epworth Sleepiness Scale and Medical Research Council dyspnoea scale.
Results: 11 (18%) of the CF patients were 'desaturators,' (SpO_2 < 90% for ≥ 30% recording time on overnight oximetry). Desaturators had greater difficulty performing their treatments (39±22 vs 61±26, p<0.01) and more exertional dyspnoea (3.2±0.8 vs 2.0±0.9, p<0.001) than non-desaturators after controlling for the effects of FEV_1, awake PaO_2 and $PaCO_2$ (adjusted p-values <0.01 and 0.04 respectively).
Conclusions: Nocturnal oxyhaemoglobin desaturation is associated with impaired QoL, independent of the effects of lung function and awake gas exchange, in stable CF outpatients with moderate to severe lung disease.

Keywords: Cystic fibrosis; Nocturnal oxygen desaturation; Quality of life

1. Background

Cystic fibrosis (CF) is characterized by a progressive decline in lung function resulting in impaired quality of life (QoL) [1]. Nocturnal oxyhaemoglobin desaturation accompanies the decline in lung function [2]. It remains unknown whether nocturnal oxyhaemoglobin desaturation is an independent predictor of impaired QoL in CF.

Nocturnal oxyhaemoglobin desaturation is common in CF subjects with severe lung disease, awake hypoxia and hypercapnia [3,4]. It appears to result from alveolar hypoventilation, impaired lung mechanics and ventilation–perfusion mismatching [5,6], which all worsen as lung function declines. Nocturnal oxyhaemoglobin desaturation has been linked to pulmonary hypertension [7], reduced sleep efficiency [8] and neurocognitive dysfunction during acute exacerbations [9]. Whether these latter effects translate into reduced QoL, independent of lung function and awake gas exchange, remains unknown.

Overnight oximetry is convenient, non-invasive and can provide an accurate, reproducible measure of overnight oxygenation in CF patients [10,11]. It has been used to detect nocturnal oxyhaemoglobin desaturation in CF patients at home [4]. Definitions vary across countries and in the published literature, but current CF guidelines recommend treatment if the oxyhaemoglobin saturation measured by pulse oximetry (SpO_2) is <88–90% for ≥10% of the night [12]. In Australia, nocturnal oxygen therapy is government-funded for patients with an $SpO_2 \leq 88\%$ for ≥30% of the night [13]. A validated CF-specific QoL instrument is now available [14].

The study hypothesis was that nocturnal oxyhaemoglobin desaturation would impact negatively on QoL in CF, independent of the effects of lung function and awake gas exchange. The aim

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* Corresponding author. Department of Allergy Immunology and Respiratory Medicine, The Alfred Hospital, Commercial Road, Melbourne, Victoria, 3004, Australia. Tel.: +61 3 9076 3770; fax: +61 3 9076 3601.
E-mail address: a.young@alfred.org.au (A.C. Young).

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was to study stable adult CF patients with moderate to severe lung disease to determine (i) the prevalence of nocturnal oxyhaemoglobin desaturation (ii) whether nocturnal oxyhaemoglobin desaturation impacted negatively on QoL (iii) if these effects occurred independent of lung function (FEV_1) and awake gas exchange (PaO_2 and $PaCO_2$) and (iv) whether a threshold existed for nocturnal oxyhaemoglobin desaturation that was associated with a reduction in QoL.

2. Methods and materials

2.1. CF patients

Written informed consent was obtained after study approval by The Alfred Hospital Institutional Ethics Committee. Consecutive outpatients were recruited from The Alfred Hospital Adult CF Service which has a statewide population base of 220 patients. Inclusion criteria were age ≥18 years, confirmed diagnosis of CF by standard criteria [12], $FEV_1 \leq 70\%$ predicted and clinical stability (no hospitalization or new antibiotics in two weeks prior). Exclusion criteria were previous domiciliary oxygen therapy or non-invasive ventilation, current sedative use, cardiac or neurological disease or symptoms of obstructive sleep apnoea.

2.2. Physiological data

Home overnight oximetry (Oxypleth, Novametrix, Connecticut, USA) was performed with a two second averaging time and sampling frequency of 0.125 Hz. Download software (Download 2001, Stowood Scientific, Oxford, UK) analysed the recording time to calculate: % recording time with $SpO_2 < 90\%$, mean SpO_2, minimum SpO_2 and mean heart rate. Patients were classified as 'non-desaturators' or 'desaturators' at two different thresholds: $SpO_2 < 90\%$ for ≥10% of the recording time (10% threshold) or $SpO_2 < 90\%$ for ≥30% of the recording time (30% threshold), based on current expert guidelines [12,13]. Awake supine arterial blood gases (ABG) were taken with a 25 gauge needle and analysed (model 865, Bayer HealthCare, NY, USA). Spirometry and lung volumes were performed (Profiler and Elite Series, Medgraphics, MN, USA) to American Thoracic Society criteria [15]. Height (cm) and weight (kg) were used to calculate body mass index (BMI).

2.3. Quality of life

Validated QoL measures assessed CF-specific domains (CF QoL Questionnaire) [14], subjective daytime sleepiness (Epworth Sleepiness Scale) [16], subjective sleep quality (Pittsburgh Sleep Quality Index) [17] and dyspnoea (Medical Research Council Dyspnoea Scale) [18]. Patients were asked if they had regularly worked or studied over the last month.

The CF QoL Questionnaire (CFQoL) is a reliable and valid measure [14]. It assesses nine functional domains: physical functioning, social functioning, treatment issues, chest symptoms, emotional responses, concerns for the future, interpersonal relationships, body image and career concerns, producing a score from 0 (worst) to 100 (best) in each. A 10 point change is considered clinically important [1]. The Epworth Sleepiness Scale (ESS) is a validated sleep questionnaire with a score >10 indicating subjective daytime sleepiness [16]. The Pittsburgh Sleep Quality Index (PSQI) assesses sleep quality and disturbance [17]. Seven components are combined to produce a global score of 0–21. A score >5 is a sensitive and specific measure of poor sleep quality. The Medical Research Council Dyspnoea scale (MRC) is a validated measure of dyspnoea in COPD [19]. It grades the effect of breathlessness on daily activities to produce five categories of perceived respiratory disability from zero (none) to four (very severe) [18]. It correlates with exercise capacity in patients with CF [20].

2.4. Statistical analysis

Data are presented as means ± 1SD or frequencies(%). Non-desaturators were compared to desaturators at the 10% and 30% thresholds. The unpaired *t*-test and Wilcoxon test (continuous variables) or Chi-square test and Fisher's Exact test (categorical variables) were used. Where a significant difference in QoL (dependent variable) was identified between non-desaturators and desaturators (independent variable) a one-way between-groups analysis of co-variance was performed to control for the effects of FEV_1, awake PaO_2 and $PaCO_2$ (covariates).

Univariate analysis was then performed using simple linear correlations to explore the relationships between mean nocturnal SpO_2, minimum nocturnal SpO_2 and QoL measures. Where a significant relationship was identified, multiple regression was performed using the QoL variable as the dependent variable and mean or minimum nocturnal SpO_2, FEV_1, and awake PaO_2 as the independent variables.

Alpha was set at 0.05 for all tests. Assuming a standard deviation of 15 points for the physical function domain of the CFQoL [21] a sample size of 18 patients was needed in each group (non-desaturator and desaturator) to detect a 10 point difference (clinically important difference) with a power of 0.8 and a two-sided α of 0.05.

3. Results

3.1. Patient characteristics

Sixty CF patients were studied. The patient demographics, FEV_1, arterial blood gases and overnight oximetry results are given in Table 1. Sixteen (27%) patients were classified as desaturators using the 10% threshold ($SpO_2 < 90\%$ for ≥10% of the recording time) whilst eleven (18%) patients were classified as desaturators using the 30% threshold ($SpO_2 < 90\%$ for ≥30% of the recording time) (Table 1).

3.2. Comparison of non-desaturators and desaturators using 10% threshold

The two groups had similar BMI and pH. Desaturators had decreased FEV_1, PaO_2, awake SaO_2 and increased $PaCO_2$ compared to non-desaturators (Table 2). Examining QoL, desaturators were not significantly different on any domain of

Table 1
Demographics and clinical parameters for CF patients.

Characteristics	CF patients
Number	60
Age, yr	31±8
Sex	36 M 24 F
BMI, kg/m^2	20.8±3.2
FEV_1, %	42±13
pH	7.41±0.03
$PaCO_2$, mm Hg	42±5
PaO_2, mm Hg	75±12
SaO_2, %	96±3
Overnight oximetry[a]	
Mean SpO_2, %	93±4
Minimum SpO_2, %	84±7
Time SpO_2<90%, %	14±27
Desaturators 10% threshold, *n* (%)	16 (27)
Desaturators 30% threshold, *n* (%)	11 (18)
Mean heart rate, beats/min	74±13

Values are mean±SD. BMI = Body mass index, Desaturators 10% threshold = Subjects spending ≥10% of recording time with SpO_2<90%, Desaturators 30% threshold = Subjects spending ≥30% of recording time with SpO_2<90%.
[a] Values are calculated for recording time overnight.

the CFQoL, ESS, global PSQI or in work/study attendance compared to non-desaturators. Desaturators did have greater exertional dyspnoea on the MRC (Table 2). However, after adjusting for the effects of FEV_1, awake PaO_2 and $PaCO_2$ these differences did not remain significant (Table 2).

3.3. Comparison of non-desaturators and desaturators using 30% threshold

Desaturators had decreased FEV_1, awake PaO_2, SaO_2 and increased $PaCO_2$ compared to non-desaturators (Table 3). Desaturators had reduced physical functioning, increased treatment issues and more chest symptoms on the CFQoL. Desaturators had more subjective daytime sleepiness on the ESS and greater exertional dyspnoea on the MRC (Table 3). After adjusting for the effects of FEV_1, awake PaO_2 and $PaCO_2$, the treatment issues domain on the CFQoL (Fig. 1) and the MRC remained significantly worse in desaturators, with a trend towards worsening for the physical functioning domain of the CFQoL (Table 3). Nocturnal oxyhaemoglobin desaturation independently explained 15%, 8% and 6% of the variance in the treatment issues domain, MRC and physical functioning domain respectively.

3.4. Correlations between nocturnal oxygen saturation and QoL

Mean nocturnal SpO_2 correlated significantly with the physical functioning domain of the CFQOL, ESS and MRC. However, none of these relationships remained significant after adjusting for the effects of FEV_1 and awake gas exchange ($PaCO_2$, PaO_2), although there was a trend towards an independent effect of mean nocturnal SpO_2 on MRC (Table 4). Minimum nocturnal SpO_2 correlated significantly

Table 2
Comparison cystic fibrosis non-desaturators vs destaurators using 10% threshold.

Characteristics	Non-desat	Desat	95% CI for difference	*p*	Adjust *p*[a]
Number, (%)	44 (73)	16 (27)			
Age, yr	30±7	31±9	−5 to 4	0.8	
Sex	25 M 19 F	11 M/5 F			
BMI, kg/m^2	21.2±3	19.8±3	−0.4 to 3	0.1	
FEV_1, %	45±11	33±13	6 to 19	<0.001	
pH	7.41±0.03	7.41±0.03	−0.02 to 0.02	0.9	
$PaCO_2$, mm Hg	40±3	46±6	−8 to −3	<0.001	
PaO_2, mm Hg	79±9	65±14	8 to 19	<0.001	
SaO_2, %	97±1	92±4	3 to 6	<0.001	
Quality of Life					
CFQoL (0=worst,100=best)					
Physical function	77±19	67±20	−2 to 21	0.1	
Social function	73±25	70±26	−12 to 18	0.7	
Treatment issues	59±26	51±27	−7 to 24	0.3	
Chest symptoms	63±27	56±23	−8 to 23	0.3	
Emotional response	73±25	77±14	−17 to 10	0.6	
Concerns for future	40±28	43±30	−20 to 14	0.7	
Relationships	55±26	53±23	−12 to 18	0.7	
Body image	57±30	55±19	−15 to 17	0.9	
Career concerns	53±30	53±26	−17 to 17	1.0	
ESS (0=best, 24=worst)	5.3±3.1	6.5±3.7	−3 to 0.7	0.2	
PSQI (0=best, 21=worst)	7.8±3.9	6.8±2.7	−1.6 to 3.7	0.4	
MRC (0=best, 4=worst)	2.0±0.9	2.8±1.0	−1.3 to −0.2	<0.01	0.4
Work or study, %	82	63		0.2	

Values are mean±SD. Non-desat = SpO_2<90% for <10% recording time, Desat=SpO_2<90% for ≥10% recording time, BMI = Body mass index, CF QoL = CF Quality of Life questionnaire, ESS = Epworth sleepiness scale, PSQI = Global score Pittsburgh Sleep Quality Index, MRC = Medical Research Council Dyspnoea Scale.
[a] Adjusted for differences in FEV_1, awake PaO_2 and $PaCO_2$.

Table 3
Comparison cystic fibrosis non-desaturators and desaturators using 30% threshold.

Characteristics	Non-desat	Desat	95% CI for difference	*p*	Adjust *p* [a]
Number, (%)	49 (82)	11 (18)			
Age, yr	30±7	31±10	−6 to 4	0.7	
Sex	28 M 21 F	8 M 3 F			
BMI, kg/m^2	21.1±3.1	19.4±3.3	−0.4 to 4	0.1	
FEV_1, %	45±11	26±8	12 to 26	<0.001	
pH	7.41±0.03	7.41±0.03	−0.02 to 0.02	1.0	
$PaCO_2$, mm Hg	41±3	47±6	−9 to −4	<0.001	
PaO_2, mm Hg	77±9	64±16	7 to 21	<0.001	
SaO_2, %	97±2	92±4	4 to 7	<0.001	
Quality of Life					
CFQoL (0=worst,100=best)					
Physical function	79±19	58±15	9 to 33	<0.01	0.07
Social function	75±25	61±26	−3 to 31	0.1	
Treatment issues	61±26	39±22	5 to 39	<0.01	<0.01
Chest symptoms	65±26	46±19	2 to 36	0.03	0.2
Emotional response	75±24	71±13	−11 to 20	0.6	
Concerns for future	42±28	37±9	−14 to 24	0.6	
Relationships	57±26	47±20	−7 to 27	0.2	
Body image	58±29	49±18	−9 to 28	0.3	
Career concerns	53±30	52±25	−19 to 21	0.9	
ESS (0=best, 24=worst)	5.1±3.0	7.6±3.8	−4.6 to −0.4	0.02	0.2
PSQI (0=best, 21=worst)	7.7±3.7	7±3	−2.5 to 3.9	0.7	
MRC (0=best, 4=worst)	2.0±0.9	3.2±0.8	−1.8 to −0.6	<0.001	0.04
Work or study, %	55	55		0.1	

Values are mean±SD. Non-desat = SpO_2<90% for <30% recording time, Desat = SpO_2<90% for ≥30% recording time, BMI = Body mass index, CF QoL = CF Quality of Life questionnaire, ESS = Epworth sleepiness scale, PSQI = Global score Pittsburgh Sleep Quality Index, MRC = Medical Research Council Dyspnoea Scale.

[a] Adjusted for differences in FEV_1, awake PaO_2 and $PaCO_2$.

with the chest symptoms domain on the CFQoL and MRC. However, none of these relationships remained significant after adjusting for the effects of FEV_1 and awake gas exchange ($PaCO_2$, PaO_2) (Table 4).

4. Discussion

The main finding in this study was that stable CF patients with moderate to severe lung disease and nocturnal oxyhaemoglobin desaturation had reduced QoL compared to 'non-desaturators'. Using the '30% threshold' (SpO_2<90% for ≥30% of the recording time on overnight oximetry) 18% of CF patients were classified as having nocturnal oxyhaemoglobin desaturation. These CF 'desaturators' had more difficulty performing treatments, greater exertional dyspnoea and trended towards a reduction in physical functioning compared to CF 'non-desaturators'. These positive findings remained significant after correcting for the effects of FEV_1, awake PaO_2 and $PaCO_2$. However, it should be acknowledged that although significant, the effect was small, with nocturnal oxyhaemoglobin desaturation

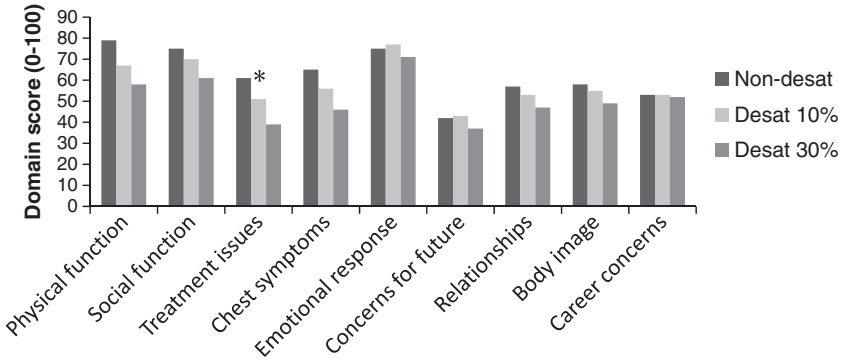

Fig. 1. Cystic Fibrosis Quality of Life Questionnaire means domain scores according to nocturnal oxyhaemoglobin saturation. * adjusted *p*-value <0.01 Non-desat vs Desat 30% (adjusted for FEV_1, awake PaO_2 and $PaCO_2$). Non-desat = Mean score for patients with SpO_2<90% for <10% recording time. Desat 10% = Mean score for patients with SpO_2<90% for ≥10% recording time. Desat 30% = Mean score for patients with SpO_2<90% for ≥30% recording time.

Table 4
Correlation between nocturnal oxygen saturation and quality of life in CF patients.

	Mean nocturnal SpO_2 ($n=60$)			Minimum nocturnal SpO_2 ($n=60$)		
Quality of life	*R*	*p*-value	Adjust *p*-value[a]	*R*	*p*-value	Adjust *p*-value[a]
CFQoL (0=worst, 100=best)						
Physical function	0.34	0.01	0.8	0.24	0.08	0.8
Social function	0.16	0.2		0.21	0.1	
Treatment issues	0.11	0.4		0.15	0.3	
Chest symptoms	0.25	0.06	0.7	0.26	0.05	0.4
Emotional response	0.01	1		0.03	0.8	
Concerns for future	−0.01	0.9		0.12	0.4	
Relationships	0.21	0.12		0.17	0.2	
Body image	0.03	0.8		0.11	0.4	
Career concerns	−0.03	0.8		−0.01	1	
ESS (0=best, 24=worst)	−0.26	0.04	0.6	−0.19	0.2	0.9
PSQI (0=best, 21=worst)	0.09	0.6		−0.01	0.9	
MRC (0=best, 4=worst)	−0.52	<0.001	0.08	−0.44	<0.01	0.2
Work or study, %	0.23	0.08	0.9	0.2	0.1	0.6

BMI = Body mass index, CF QoL = CF Quality of Life questionnaire, ESS = Epworth sleepiness scale, PSQI = Global score Pittsburgh Sleep Quality Index, MRC = Medical Research Council Dyspnoea Scale.
[a] *p*-value adjusted for FEV_1, awake PaO_2 and $PaCO_2$.

independently explaining between 6 and 15% of the variance in these parameters. No effect was seen on QoL at the '10% threshold' ($SpO_2<90\%$ for $\geq 10\%$ of the recording time) or when correlated against continuous measures of nocturnal SpO_2. These findings suggest that nocturnal oxyhaemoglobin desaturation at the 30% threshold has an independent effect on QoL in CF.

Previous studies found a similar prevalence of nocturnal oxyhaemoglobin desaturation in CF. CF subjects with an $FEV_1<60\%$ predicted spent 30% of the night with an $SpO_2<90\%$ [22]. Another study of 70 adult CF patients with FEV_1 20–100% predicted detected nocturnal oxyhaemoglobin desaturation (defined as $SpO_2<90\%$ for >5% of sleep time) in 40% of subjects [4]. However, the only randomised placebo-controlled trial of long-term nocturnal oxygen therapy in CF demonstrated no improvement in QoL, although there was better maintenance of school and work attendance with treatment [23]. Of note, patients in this trial had moderate not severe daytime hypoxemia ($PaO_2<65$ mm Hg), had no assessment for nocturnal oxyhaemoglobin desaturation, received oxygen therapy for a mean of seven hours per night and were assessed with non-standardised questionnaires, all of which could have contributed to the negative result.

This study utilised home overnight oximetry rather than laboratory-based polysomnography as it was more convenient, less invasive and therefore less likely to limit recruitment. Arterial pulse oximetry can provide a reproducible measure of nocturnal oxygenation in patients with CF [24]. A study of CF patients with pulse oximetry in the hospital setting revealed little night to night variability [11]. Similar consistency was demonstrated using overnight oximetry in CF subjects at home [10].

The choice of the 10% and 30% thresholds to define nocturnal oxyhaemoglobin desaturation in this study were based on national and international guidelines which recommend implementing nocturnal oxygen therapy at varying levels of hypoxia. The CF consensus conference guidelines recommend nocturnal oxygen therapy when the SpO_2 is <88–90% for $\geq 10\%$ of the night [12]. Australian guidelines for domiciliary oxygen use in chronic lung disease, which determine local funding approval, recommend nocturnal oxygen therapy when the SpO_2 is $\leq 88\%$ for more than a third of the night [13]. However, it must be acknowledged that the definition of what constitutes nocturnal oxyhaemoglobin desaturation will vary from country to country and centre to centre due to the lack of evidence supporting cutoffs for treatment and clinical significance. Whether nocturnal oxyhaemoglobin desaturation carries any clinical significance in CF patients at any level has been the subject of controversy [25]. Given the limited trial data supporting nocturnal oxygen therapy in CF, the current study investigated whether a threshold for nocturnal oxyhaemoglobin desaturation existed that was associated with clinical deterioration. The findings indicated the 30% threshold, but not the 10% threshold, was associated with impaired QoL. However, further research is clearly required to determine if nocturnal oxygen therapy is beneficial in CF.

Mean and minimum nocturnal SpO_2 levels have also been used as a measure of nocturnal oxyhaemoglobin desaturation in CF [5,26]. Therefore, data was also analysed in the current study using continuous measures of nocturnal oxyhaemoglobin desaturation. There was no observed effect of mean or minimum nocturnal SpO_2 on QoL. A possible explanation is that the detrimental effects of nocturnal oxyhaemoglobin desaturation may become apparent when the SpO_2 falls below 90%. Alternatively, the skewing of these values towards the upper end of the scale at 90 to 100% may make it difficult to demonstrate an effect using linear correlations.

It is interesting to speculate on how nocturnal oxyhaemoglobin desaturation might influence QoL in CF. In the current study, nocturnal oxyhaemoglobin desaturation was associated with greater difficulty in performing treatments, increased exertional dyspnoea and trended towards a reduction in physical functioning. Nocturnal oxyhaemoglobin desaturation has been

associated with sleep fragmentation and neurocognitive dysfunction in CF [8,9], both of which could reduce treatment adherence. Nocturnal oxyhaemoglobin desaturation has also been linked to the presence of pulmonary hypertension in CF [7], which could increase exertional dyspnoea and reduce exercise capacity.

The strengths of this study included assessment of patients during periods of clinical stability to limit the variability in nocturnal oxyhaemoglobin desaturation which occurs during CF exacerbations [9]. The sample size allowed for correction of the main collinear confounding factors, namely lung function and awake gas exchange. The use of CF-specific validated questionnaires, which have only recently become available, have added to the legitimacy of the study findings. Analysis of nocturnal oxyhaemoglobin desaturation at the 10% and 30% thresholds determined a level at which clinical deterioration could occur.

There are several weaknesses of this study which need to be considered. The design was cross-sectional and thus cannot be used to provide evidence of causation. The study was underpowered as 18 patients were required in both the non-desaturator and desaturator groups. Thus, negative findings may reflect false negatives due to the sample size. Correction for the main confounding factors of lung function and awake gas exchange were undertaken, but other factors may explain the differences in QoL. In CF, there is often a collinear relationship between disease variables that tend to worsen in parallel. A larger sample size would be required to correct for all possible confounding factors. Polysomnography was not used to record differences in sleep architecture which could have contributed to the observed effects. Measurement of pulmonary arterial pressures and neurocognitive testing may have provided useful information on the mechanisms linking nocturnal oxyhaemoglobin desaturation to impaired QoL.

In conclusion, this study has demonstrated clinically significant nocturnal oxyhaemoglobin desaturation in 18% of stable CF patients with moderate to severe lung disease using a cutoff of $SpO_2 < 90\%$ for $\geq 30\%$ of the recording time on overnight oximetry. Desaturators had impaired QoL compared to non-desaturators after correcting for the effects of FEV_1, awake PaO_2 and $PaCO_2$. An $SpO_2 < 90\%$ for $\geq 30\%$ of the recording time on overnight oximetry appeared to be a clinically relevant threshold for nocturnal oxyhaemoglobin desaturation, but trials of treatment with nocturnal oxygen are required to confirm this assumption.

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Conflict of interest statement

None of the authors have any conflicts of interest to declare.

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